

Hazardous Waste Special Topics

**Energy and Environment Cabinet
Department for Environmental Protection**

Division of Waste Management



To Protect and Enhance Kentucky's Environment

Kentucky
UNBRIDLED SPIRIT™

Pharmaceutical Waste

**Pharmaceuticals are just another
hazardous waste!**



Pharmaceutical Waste

When Pharmaceuticals Become Waste

- A pharmaceutical is considered waste at the time and place the decision is made to discard it.
- A waste determination must be conducted on a discarded pharmaceutical to determine if it is hazardous waste.
 - Spilled, damaged or broken product no longer useable for the intended purpose.
 - An item used in cleaning spills (dry absorbent, paper towels, etc.) must be determined and managed as either hazardous or non-hazardous waste



Pharmaceutical Waste

When Pharmaceuticals are not a Waste

- Returned for documented credit through the pharmaceutical reverse distribution system to a manufacturer, wholesaler or reverse distributor due to an;
- Oversupply
- Expiration of the recommended shelf life
- Manufacturer recall
- Product received as a result of a shipping error, or
- Product is damaged.
- Donated to a charitable organization as described in the Internal Revenue Code
- No decision to discard



Pharmaceutical Waste

How pharmaceutical wastes may be generated:

- Expiration date reached before use (about 3% of all drugs)
- Spill cleanup debris
- Partially used vials from IV prep
- Partially used vials from filling syringes
- Compounding
- Excess medication eliminated from overfilled syringes
- Used syringes and IVs (biohazards if empty, considered to be containers)
- Discontinued or unused preparations
- Unused doses
- Unused medication after treatment is completed
- P-listed pharmaceutical packages



Pharmaceutical Waste

Where Pharmaceutical Waste is Generated

- Surgery
- Pharmacy
- Patient Room
- Emergency Room
- Intensive Care
- Oncology
- Hematology
- Radiology
- Out-patient clinic



P-listed and U-listed Pharmaceuticals

<u><i>Name</i></u>	<u><i>Hazardous Waste Number</i></u>	<u><i>Name</i></u>	<u><i>Hazardous Waste Number</i></u>
Arsenic trioxide	P012	Hexachlorophene	U132
Epinephrine	P042	Lindane	U129
Nicotine	P075	Melphalan (chemo)	U150
Nitroglycerin ¹	P081	Mercury	U151
Physostigmine	P204	Mitomycin C (chemo)	U010
Physostigmine salicylate	P188	Paraldehyde (CIV)	U182
Warfarin >0.3%	P001	Phenacetin	U187
Chloral Hydrate (CIV) ²	U034	Phenol	U188
Chlorambucil (chemo)	U035	Reserpine	U200
Chloroform	U044	Resorcinol	U201
Cyclophosphamide (chemo)	U058	Saccharin	U202
Daunomycin (chemo)	U059	Selenium sulfide	U205
Dichlorodifluoromethane	U075	Streptozotocin (chemo)	U206
Diethylstilbestrol	U089	Trichloromonofluoromethane	U121
Formaldehyde	U122	Uracil mustard (chemo)	U237
		Warfarin <0.3%	U248



Common P-listed

➤ Warfarin >0.3% (P001)

Brand names: Coumadin, Jantoven, Marfarin

- Container residues.
- Contaminated wipes.
- Discarded Products.

➤ Nicotine (P075)

Brand names: Nicoderm CQ, Nicorette, Nicotrol, Habitrol

- Unused discarded products. (RO# 14817)



Other P-listed

➤ Nitroglycerine (P081)

If medicinal nitroglycerine does not exhibit the characteristic of reactivity (for which it was listed), then it is not considered a listed hazardous waste. [RO# 14654](#)

➤ Phentermine (P046) Base chemical only. Appetite suppressant.

➤ Physostigmine (P204)

Ophthalmic solution, trans dermal patches, ointment.



Other P-listed

- **Arsenic trioxide (P012)**
Trisenox Injection – Chemotherapy for acute promyelocytic leukemia.
- **Epinephrine base (P042)**
EPA has clarified that epinephrine salts are not included in the P042 listing.
(RO# 14778)
- **Physostigmine salicylate (P188) - Injection, intravenous.**



D-List Chemicals in Pharmaceuticals

<u><i>Name</i></u>	<u><i>Hazardous Waste No.</i></u>	<u><i>Regulatory Level (mg/L)</i></u>
Arsenic	D004	5.0
Barium	D005	100.0
Cadmium	D006	1.0
Chloroform	D022	6.0
Chromium	D007	5.0
M-Cresol	D024	200.0
Lindane	D013	0.4
Mercury	D009	0.2
Selenium	D010	1.0
Silver	D011	5.0



ICR Wastes

- Ignitable pharmaceutical wastes - Erythromycin gel 2%, Texacort solution 1%, flexible collodion, Amyl nitrite inhalers, Silver nitrate applicators, Primatene aerosol, discarded products containing alcohol $\geq 24\%$.
- Corrosive - $\text{pH} \leq 2$ or ≥ 12.5 Could occur if the pharmacy compounds medications on-site.
- Reactive - Nitroglycerine? Dosage forms are exempted.



D-List Chemicals in Pharmaceuticals

- **Mercury**
 - Elemental mercury in thermometers and sphygmomanometers.
- **Mercury compounds - Thimerosal and phenylmercuric acetate.**
 - preservative in vaccines, eye drops , nasal sprays.
- **Arsenic compounds - Carbasone (STD treatment), there are others but they are not common.**
- **Barium compounds - Barium sulfate (Used in radiology)**



Management of Empty Containers

- A container that held a **P-listed** CCP must be managed as a HW, unless the container is rendered “RCRA empty” (see 40 CFR 261.7(b)(3)). RCRA empty for a P-listing = the container has been triple-rinsed. Rinsate must be managed as HW.
 - **Count only the weight of the residue toward generator status.**
 - Estimated that residue in a 100-count container is ≤ 1 mg.
 - It would take the combined residues from > 1 million dispensed bottles to reach LQG quantities of > 1 kg/month.
- (RO# 14827)



Management of Empty Containers

- Hazardous Waste Manifests usually list the entire weight of the packaging, empty bottle, and residue.

Box 14 - Special Handling Instruction and Additional Information may note that the manifest lists the total weight of containers but is not used to determine generator status.

- Don't require registration as a Large Quantity Generator if the P-listed line item exceeds 2.2 pounds.



Management of Empty Containers

- A container that held a **U-listed** CCP or a characteristic HW is RCRA empty and is not a HW when (40 CFR 261.7(b)(1)): All of the pharmaceutical has been removed that can be removed by normal means; AND no more than 3% by weight of the total capacity of the container remains.
- When it is empty, throw it away.



Aerosol Cans

They consist of three different types of materials:

- Liquid product in the can.
- Gaseous propellant in the can.
- The can itself.



Aerosol Cans

Scrap Metal Exemption

- If you plan to recycle punctured cans as scrap metal:
 - Setup a satellite accumulation container with a puncture station to safely drain can residues.
 - Label container “Hazardous Waste” or other words to describe contents.
 - Recycle punctured aerosol cans as scrap metal.



Aerosol Cans

Disposal of aerosol cans after puncturing

- *You must receive approval for on-site treatment!*
- Setup a satellite accumulation container with a puncture station to safely drain can residues.
- Label container “Hazardous Waste” or other words to describe contents.
- Dispose of cans as solid waste.



Aerosol Cans

Disposal of aerosol cans without puncturing

- Setup satellite accumulation container.
- Ship as hazardous waste.



Solvent Wipes Rule

- Kentucky has not adopted the new solvent wipes rule!
- You may apply for a variance. A request for variance from a requirement of the waste management administrative regulations shall be submitted in a report in sufficient detail to satisfy a request from the cabinet to provide the analyses, procedures, controls, and other pertinent data necessary to support the request for variance (401 KAR 30:020 Section 2)



Solvent Wipes Rule

The final rule provides a definition for “**wipe**” and “**solvent-contaminated wipe**” in 40 C.F.R. 260.10.

- ***Wipe*** means a woven or non-woven shop towel, rag, pad, or swab made of wood pulp, fabric, cotton, polyester blends, or other material.
- ***Solvent-contaminated wipe*** means a wipe that, after use or after cleaning up a spill, either:
 - Contains one or more of the F001 through F005 solvents;
 - Exhibits a hazardous characteristic when that characteristic results from a listed solvent; or
 - Exhibits only the hazardous waste characteristic of ignitability due to the presence of solvents that are not listed.



Solvent Wipes Rule

- Solvent-contaminated wipes that contain listed hazardous waste other than solvents, or exhibit the characteristic of toxicity, corrosively, or reactivity due to contaminants other than solvents, **are not eligible for the exclusions.**
- Specifically, the rule includes:
 - A conditional exclusion from the **definition of solid waste** for solvent-contaminated wipes sent for cleaning (“**reusable wipes**”) – 40 C.F.R. 261.4(a)(26).
 - A conditional exclusion from the **definition of hazardous waste** for solvent-contaminated wipes sent for disposal (“**disposable wipes**”) – 40 C.F.R. 261.4(b)(18)



Solvent Wipes Rule

Storage

- Solvent-contaminated wipes must be accumulated, stored, and transported in non-leaking, closed containers.
- The containers must be able to contain free liquids, if they occur (for example, from compression of the wipes).
- Containers must be closed except when adding or removing wipes.
- **A container must be sealed when the container is full, when the wipes are no longer being accumulated, and during transportation.**



Solvent Wipes Rule

- Wipes accumulated in an open-head drum or container would be considered closed when the cover makes complete contact between the fitted lid and the rim.
- After accumulation and during transport, this same container must be sealed to meet this standard; thus, the rings must be clamped or bolted to the container.

Note, these examples are consistent with EPA's closed container guidance (RCRA online 14826, 12/3/2009, and 11/2/2011).



Solvent Wipes Rule

Other examples that may meet the closed container standard:

- Containers with covers opened by a foot pedal (e.g. flip top or spring loaded lid) or with a self closing swing door;
- Bags can be used, provided they meet the standard (i.e. the neck of the bag is tightly bound and sealed, the bag is able to contain liquids, and is non-leaking).

Examples that **do not meet** the standard:

- Bags leaving a trail of liquid on the ground;
- **Cardboard boxes.**



Solvent Wipes Rule

Labeling

- Containers of solvent-contaminated wipes must be labeled:

“Excluded Solvent-Contaminated Wipes”

- Containers must be labeled during accumulation, storage, and transportation



Solvent Wipes Rule

Accumulation Time Limit

- Solvent-contaminated wipes may be accumulated by the generator for up to 180 days from the start date of accumulation for each container.
- Generators must keep documentation that the 180-day accumulation time limit is being met.



Solvent Wipes Rule

No free liquids – the Heart of the Rule

- Solvent-contaminated wipes **may not** contain free liquids **at the point of being sent** for cleaning onsite or sent offsite for cleaning or disposal.
- “No free liquids” is defined in 260.10 and is determined using the paint filter liquids test (Method 9095B in SW-846).
- Generators must document the process they are using to meet the no free liquids condition.
- **Free liquid spent solvent that is removed from the wipes is subject to hazardous waste regulation.**



Solvent Wipes Rule

Recordkeeping

Generators must maintain the following documentation at their site:

- Name and address of the destination facility (laundry, combustor, or landfill) that is receiving the solvent-contaminated wipes;
- Documentation that the 180-day accumulation time limit is being met:
 - Could include a service contract specifying frequency of pick-up, a log that lists the start date of each container, or container labels with the start date.
- Description of the process the generator is using to meet the “no free liquids” condition:
 - Description of technologies, methods, sampling, or knowledge that a generator is using to ensure wipes container no free liquids at the point of transport.



Solvent Wipes Rule

Handling Facilities

- **Reusable wipes** must be sent to a laundry or dry cleaner whose discharge, if any, is regulated under section 301 (effluent discharge restriction) and 402 (permitting requirements) or section 307 (indirect discharge to a POTW) of the clean water act.
- **Disposable wipes** must go to either
 - A combustor regulated under section 129 of the clean air act or a hazardous waste combustor, boiler, or industrial furnace regulated under 40 CFR 264, 265, or 266 subpart H; or
 - A municipal solid waste landfill regulated under 40 CFR 258 or a hazardous waste landfill regulated under 40 CFR 264 or 265.
- Storage/labeling requirement continue to apply if solvent-contaminated wipes are stored at handlers.

Any free liquids found by handling facilities must be removed and managed as hazardous waste!



Solvent Wipes Rule

For more information on this rulemaking,
(website includes a summary chart of the rule
as well as FAQs) go to:

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[http://www.epa.gov/epawaste/hazard/wastetypes/
wasteid/solvents/wipes.htm](http://www.epa.gov/epawaste/hazard/wastetypes/wasteid/solvents/wipes.htm)



Upcoming Regulations



Division of Waste Management

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